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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE SELENIOUS ACID LITIGATION	C.A. No. 2:24-cv-07791 (BRM) (CLW) (Consolidated)

PLAINTIFF'S ANSWER TO DEFENDANTS SOMERSET THERAPEUTICS, LLC, SOMERSET PHARMA, LLC, AND ODIN PHARMACEUTICALS, LLC'S ANSWER, SEPARATE DEFENSES, JURY DEMAND AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff American Regent, Inc. ("ARI"), by its undersigned attorneys, hereby responds to the Answer, Affirmative Defenses, and Counterclaims of Defendants Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (collectively "Somerset" or "Defendant"), (ECF No. 75; hereinafter, the "Counterclaims") as follows:

GENERAL DENIAL

ARI denies all allegations in Somerset's Counterclaims except for those specifically

admitted below. With respect to the allegations made in the Counterclaims, upon knowledge with respect to ARI's own acts, and upon information and belief as to other matters, ARI responds and alleges as follows:

THE PARTIES

1. On information and belief, American Regent, Inc. is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Admitted.

2. On information and belief, Somerset Therapeutics, LLC is a limited liability corporation organized under the laws of the State of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873.

ANSWER: On the basis of Somerset's Answer to Paragraph 3 in the Counterclaims, admitted.

3. On information and belief, Somerset Pharma, LLC is a limited liability corporation organized under the laws of the State of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873.

ANSWER: On the basis of Somerset's Answer to Paragraph 4 in the Counterclaims, admitted.

4. On information and belief, Defendant Odin Pharmaceuticals, LLC, is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873.

ANSWER: On the basis of Somerset's Answer to Paragraph 7 in the Counterclaims, admitted.

JURISDICTION AND VENUE

5. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 5 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Somerset purports to bring the Counterclaims

under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI specifically denies that the Counterclaims have merit or that Somerset is entitled to any relief on its Counterclaims.

6. This Court has personal jurisdiction over Counterclaim Defendant/Plaintiff on the basis of, *inter alia*, their contacts with New Jersey relating to the subject matter of this action, including having filed suit.

ANSWER: Paragraph 6 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest personal jurisdiction in this judicial district for the purposes of this action only.

7. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

ANSWER: Paragraph 7 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest venue in this judicial district for the purposes of this action only.

BACKGROUND

8. On information and belief, ARI holds approved New Drug Application ("NDA") No. 209379 for Selenious Acid brand trace element injection.

ANSWER: Admitted.

9. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

ANSWER: Paragraph 9 states legal conclusions for which no response is required. To the extent a response is required, admitted.

10. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

ANSWER: Paragraph 10 states legal conclusions for which no response is required. To the extent a response is required, admitted.

11. U.S. Patent 12,150,957 ("the '957 patent"), titled "Trace Element Compositions, Methods of Making and Use," issued on November 26, 2024.

ANSWER: Admitted.

12. On information and belief, American Regent, Inc. is the assignee of the '957 patent.

ANSWER: Admitted.

13. Upon information and belief, Counterclaim Defendant/Plaintiff caused the '957 patent to be listed in the Orange Book as a patent that claims such a drug for which ARI submitted NDA No. 209379.

ANSWER: Admitted.

14. Somerset Therapeutics, LLC submitted Abbreviated New Drug Application ("ANDA") No. 218780 ("Somerset ANDA") to obtain FDA approval to market a generic version of Selenious Acid products ("Somerset's ANDA Product") prior to the expiration of the '957 patent.

ANSWER: ARI admits that Somerset notified ARI that Somerset submitted ANDA No. 218780 to market a generic version of ARI's Selenious Acid product prior to the expiration of the '957 patent. ARI otherwise denies the allegations in Paragraph 14.

15. By letters dated June 11, 2024 and November 19, 2024 (collectively the "Somerset '565 Patent Notice Letters"), pursuant to 21 U.S.C. § 355(j)(2)(B), Somerset Therapeutics, LLC notified Counterclaim Defendant/Plaintiff that ANDA No. 218780 includes a Paragraph IV Certification with respect to the '565 patent. The Somerset '565 Patent Notice Letters, which are incorporated herein by reference, each contained a detailed statement of the factual and legal bases for Somerset Paragraph IV Certification that the claims of the '565 patent are invalid, not infringed, and/or unenforceable.

ANSWER: ARI admits that, by letters dated June 11, 2024 and November 19, 2024 ("the '565 Patent Notice Letters"), Somerset notified ARI that Somerset submitted ANDA No. 218780 to market a generic version of ARI's Selenious Acid product, intravenous ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and (2) eq. 12 mcg/2 mL (eq. 6 mcg/mL)), prior to the expiration of the '565 patent. ARI further admits that the '565 Patent Notice Letters informed

ARI that ANDA No. 218780 includes a Paragraph IV Certification with respect to the '565 patent. ARI further admits that the '565 Patent Notice Letters contained arguments and/or positions that the '565 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Somerset's factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 15.

16. By letter dated December 20, 2024 (the "Somerset '957 Patent Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Somerset Therapeutics, LLC notified Counterclaim Defendant/Plaintiff by letter that ANDA No. 218780 includes a Paragraph IV Certification with respect to the '957 patent. The Somerset '957 Patent Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Somerset Paragraph IV Certification that the claims of the '957 patent are invalid, not infringed, and/or unenforceable.

ANSWER: ARI admits that, by letter dated December 20, 2024 ("the '957 Patent Notice Letter"), Somerset notified ARI that Somerset submitted ANDA No. 218780 to market a generic version of ARI's Selenious Acid product, intravenous ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and (2) eq. 12 mcg/2 mL (eq. 6 mcg/mL)), prior to the expiration of the '957 patent. ARI further admits that the '957 Patent Notice Letter informed ARI that ANDA No. 218780 includes a Paragraph IV Certification with respect to the '957 patent. ARI further admits that the '957 Patent Notice Letter contained arguments and/or positions that the '957 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Somerset's factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 16.

17. On December 13, 2024, Counterclaim Defendant/Plaintiff filed this instant lawsuit alleging infringement of the '957 patent.

ANSWER: Admitted.

COUNT I
(Declaratory Judgment of Non-Infringement of the '957 Patent)

18. Somerset re-alleges and incorporates by reference the allegations in Paragraphs 1 through 17 of its Counterclaims as though fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

19. Counterclaim Defendant/Plaintiff allege ownership of the '957 patent and have brought claims against Somerset alleging infringement of the '957 patent.

ANSWER: Admitted.

20. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Somerset's ANDA and/or the commercial marketing of Somerset's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '957 patent.

ANSWER: Paragraph 20 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that there is an actual, substantial, and continuing and justiciable case and controversy between ARI and Somerset regarding Somerset's infringement of the '957 patent. ARI specifically denies that there is an actual, substantial, and continuing justiciable case and controversy between ARI and Somerset regarding invalidity or unenforceability of the '957 patent. ARI specifically denies that the Counterclaims have merit or that Somerset is entitled to any relief on its Counterclaims.

21. Somerset has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '957 patent and is not liable for such infringement.

ANSWER: Denied.

22. Somerset is entitled to a declaration that the manufacture, use, or sale of Somerset's ANDA Product would not infringe any valid or enforceable claim of the '957 patent.

ANSWER: Denied

COUNT II
(Declaratory Judgment of Invalidity or Unenforceability of the '957 Patent)

23. Somerset re-alleges and incorporates by reference the allegations in Paragraphs 1 through 22 of its Counterclaims as though fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

24. Counterclaim Defendant/Plaintiff allege ownership of the '957 patent and have brought claims against Somerset alleging infringement of the '957 patent.

ANSWER: Admitted.

25. One or more claims of the '957 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

ANSWER: Denied.

26. The '957 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

ANSWER: Denied.

27. The alleged invention of the '957 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '957 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '957 patent and would have had a reasonable expectation of success in doing so.

ANSWER: Denied.

28. The subject matter claimed in the '957 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

ANSWER: Denied.

29. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Somerset's ANDA and/or the commercial marketing of Somerset's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '957 patent.

ANSWER: Paragraph 29 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is an actual, substantial, and continuing justiciable case and controversy between ARI and Somerset regarding Somerset's infringement of the '957 patent. ARI specifically denies that there is an actual, substantial, and continuing justiciable case and controversy between ARI and Somerset regarding invalidity or unenforceability of the '957 patent.

30. Somerset is entitled to a declaration that all claims of the '957 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

ANSWER: Denied.

PRAYER FOR RELIEF

ARI denies that Somerset is entitled to any judgment or relief against ARI and, therefore specifically denies Paragraphs (a)–(e) of Counterclaimant Somerset's Prayer for Relief.

Each averment and/or allegation contained in Somerset's Counterclaims that is not specifically admitted herein is hereby denied.

ARI requests that judgment be entered in its favor, dismissing Somerset's Counterclaims with prejudice, awarding ARI's attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

Dated: January 28, 2025

By: s/ Charles H. Chevalier

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CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2025, a true and correct copy of Plaintiff's Answer to Defendant Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC's Answer, Separate Defenses, Jury Demand and Counterclaims to Complaint for Patent Infringement was served by ECF on all counsel of record and electronic mail on all counsel of record for Somerset.

Date: January 28, 2025

s/ Charles H. Chevalier

Charles H. Chevalier